

Remarks

Claims 1-15 were pending in this application. By this Amendment, claims 10-13 and 15 are canceled without prejudice to prosecution in another application. Claims 1 and 6 are amended. Support for these amendments can be found throughout the specification, including at least at page 3, paragraph 009, page 9, paragraph 0032 and page 26, paragraph 0074 to page 27, paragraph 0076. New claims 16-21 are added. Support for the new claims can be found throughout the specification, including at least at page 3, paragraph 009 and page 7, paragraph 0025.

No new matter is introduced by the foregoing amendments. After entry of this Amendment, **claims 1-9, 14, and 16-21 are pending in this application**. Consideration of the pending claims is requested.

Elections/Restrictions

Applicants note that the Office has acknowledged the election of Group I, claims 1-9 and 14, and that the Office has made the election final. Claims 10-13 and 15 are canceled as drawn to non-elected subject matter.

Information Disclosure Statement

Applicants thank Examiner Kumar for considering the references cited on the Information Disclosure Statement submitted to the United States Patent and Trademark Office on February 1, 2007. Applicants note that the signed copy of the corresponding Form-1449 does not indicate that PCT Application No. WO 01/083697 (Exelixis Plant Sciences, Inc.) was considered. Thus, Applicants respectfully request that the Office indicate in a subsequent communication that this reference has been considered. A copy of the appropriate page of the Form-1449 is provided herewith, for the Examiner's convenience.

Claim Objections

Claims 1 and 6 are objected to for alleged informalities in reciting "control plants". Claims 1 and 6 have been amended to recite "... relative to a plant of the same species that does not comprise the plant transformation vector". Applicants submit that by these amendments, the

nature of the “control plants” is sufficiently formalized. Applicants respectfully request that the claim objections be withdrawn.

Rejections under 35 U.S.C. §112, second paragraph

Claims 1-9 and 14 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection.

The Office alleges that claims 1 and 6, and dependent claims 2-5, 7-9, and 14 are indefinite in reciting “an ortholog thereof” in relation to SEQ ID NO: 2, because the “use of the term ‘ortholog’ in the claim does not set forth the metes and bounds of the claimed invention” (Office action, page 4). Applicants respectfully disagree. However, solely to advance prosecution in this case, Applicants have removed reference to the term “ortholog” from independent claims 1 and 6, thereby making these rejections moot.

The Office also alleges that claim 6, and dependent claims 7 and 8 are indefinite in reciting the production of a plant with “an altered oil content phenotype” when the claim is directed to “a method of producing a high oil phenotype in a plant”. Applicants respectfully disagree. However, solely to advance prosecution in this case, Applicants have substituted the phrase “high-oil phenotype” for “an altered oil content phenotype”, in independent claim 6, thereby making these rejections moot.

The Office also alleges that claim 9 is indefinite in reciting “direct progeny” and “indirect progeny”. Applicants respectfully disagree. Applicants submit that the terms “direct progeny” and “indirect progeny” are not confusing because both terms are defined in the specification at page 6, paragraph 0021. The specification states that, “direct progeny of a given plant derives from the seed (or, sometimes, other tissue) of that plant and is in the immediately subsequent generation.” Additionally, “indirect progeny of a given plant derives from the seed (or other tissue) of the direct progeny of that plant or from the seed (or other tissue) of subsequent generations in that lineage.” Thus, in light of the specification, the meanings of “direct progeny” and “indirect progeny” are clear. Applicants respectfully request that this rejection be withdrawn.

In light of the above arguments and the amendments made herewith, Applicants respectfully request that the indefiniteness rejections be withdrawn.

Claim Rejections under 35 U.S.C. §112, first paragraph (enablement)

Claims 1-9 and 14 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The claims are rejected because the specification allegedly “does not reasonably provide enablement for (i) a transgenic plant with increased oil content or a method of producing said transgenic plant comprising a nucleotide sequence that encodes an ortholog of SEQ ID NO: 2 and (ii) a transgenic plant with increased oil content or a method of making said transgenic plant comprising a nucleotide sequence which is complementary to a nucleotide sequence that encodes SEQ ID NO: 2” (Office action, page 6). Applicants respectfully traverse this rejection. In spite of this, and solely to advance prosecution in this case, claims 1 and 6 are amended, as discussed below. It is believed that the amended claims and the claims dependent thereon are fully enabled by the specification.

Claims 1 and 6 have been amended to be directed to a transgenic plant and a method of producing a high oil phenotype in a plant, comprising in part, “a plant transformation vector comprising . . . an amino acid sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO: 2”. Claims 1 and 6 have also been amended to remove the reference to a complementary sequence element. At least this portion of the present rejections should be withdrawn.

The Office asserts that “[m]aking amino acid substitutions in SEQ ID NO: 2 is unpredictable . . . [because] the positions within the protein’s sequence where such amino acid changes can be made with a reasonable expectation of success (without altering protein function) are limited ” (Office action, page 9). The Office further asserts that “identification of related sequences that will encode enzymes having a particular catalytic activity is particularly problematic in the enzymes involved in modifying fatty acids” (Office action, page 10). But the question is not what effect a random mutation might have on the function of a protein sequence. Instead, it is whether the instant specification allows one of ordinary skill in the art to make and

use a plant comprising a nucleotide sequence that (1) encodes a polypeptide sequence that has at least 95% sequence identity with SEQ ID NO: 2, and that (2) conveys a high oil phenotype on the plant. Applicants provide sufficient teachings in the specification, particularly in view of the level of skill of those in the art, to enable the scope of the invention as currently claimed.

The Federal Circuit has repeatedly stated that enablement is not precluded by the necessity for some experimentation, so long as the experimentation is not undue. *In re Wands* 8 USPQ2d 1400 (Fed. Cir. 1988). A considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance in which the experimentation should proceed. *Id.* The specification (see page 11, paragraph 0037 through page 12, paragraph 0038) clearly describes methods, which were well known to those of skill in the art at the time the application was filed, for identifying and producing sequence variants, namely:

- (i) Sequence homology analysis, using BLAST and CLUSTAL programs, for example;
- (ii) Nucleic acid hybridization;
- (iii) Degenerate PCR and screening of a cDNA or genomic library;
- (iv) Antibody binding and expression libraries; and
- (v) Site directed mutagenesis.

Applicants point out that the requirement of at least 95% sequence identity to SEQ ID NO: 2 provides very predictable and defined structure for the sequences encompassed by the claims. This claimed percentage identity and the size of SEQ ID NO: 2 permits only up to 16 amino acid changes within the full-length 326 amino acid protein which can be readily produced, identified, and characterized by the above methods.

Significantly, the specification also teaches how any identified sequence of interest, such as SEQ ID NO: 2 and sequences having at least 95% sequence identity to SEQ ID NO: 2, can be used to generate plants with high oil phenotype and how to test for high oil content in transgenic plants transformed with such a sequence. For example, the identified sequence can be cloned into an over-expression vector which in turn can be used to generate transgenic plants. Such

plants can then be tested for high oil phenotype compared to non-transgenic plants, as measured with NIR infrared spectroscopy (Example 5 at page 26, paragraphs 0073 and 0074). Therefore, undue experimentation is not required to make and use a plant transformed with a nucleotide sequence that encodes a polypeptide sequence that has at least 95% sequence identity with SEQ ID NO: 2, and that conveys a high oil phenotype in the plant.

Applicants respectfully submit that in view of the teachings of the specification, and the knowledge of one of skill in the art at the time the application was filed, claims 1 and 6 (and claims dependent thereon) are fully enabled. In light of the arguments presented above and the amendments of the claims, Applicants request that the rejections of claims 1-9 and 14 under 35 U.S.C. §112, first paragraph be withdrawn.

Applicants thank the Examiner for acknowledging that the claims are enabled for a transgenic plant and a method of making a transgenic plant comprising a plant transformation vector “comprising the amino acid sequence set forth as SEQ ID NO: 2”. Therefore, claims 17, 18, 20, and 21, are enabled.

Rejections under 35 U.S.C. §112, first paragraph (written description)

Claims 1-9 and 14 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection. In spite of this, and solely to advance prosecution in this case, independent claims 1 and 6 are amended herewith and it is believed that the amendments clearly overcome the rejection, as discussed below.

The Office alleges that the claims are directed to a “broadly claimed genus [which] encompasses structures whose function is unrelated to the instantly claimed SEQ ID NO: 2” (Office action, page 15). The Office further alleges that “the only species described in the specification is SEQ ID NO: 1, which encodes SEQ ID NO: 2” and that “one of skill in the art would not recognize that Applicant was in possession of the necessary common attributes of the

genus in view of the disclosed species” (*Id.*). Based on these statements, the Office concludes that the specification does not provide sufficient written descriptive support for the claims.

Applicants respectfully disagree that more than one sequence is necessary to establish adequate written description for a genus, at least for the following reasons.

As established in *Ex parte Parks*, “adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. . . . Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed” *Ex parte Parks*, 30 USPQ2d 1234, 1236-37 (B.P.A.I. 1993) (emphasis added). Moreover, the MPEP at §2163 states that “[w]hat is conventional or well known to one of skill in the art need not be disclosed in detail. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384; 231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. *See, e.g. Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating “description need not be in *ipsis verbis* [i.e., “in the same words”] to be sufficient”).”

In the current instance, amended claims 1 and 6 recite “a plant transformation vector comprising . . . a nucleotide sequence that encodes a HIO32.3 polypeptide comprising . . . the amino acid sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO:2”. This language clearly and structurally describes the molecules that fall within the claimed subject matter. Moreover, the original disclosure clearly conveys that Applicants had possession of the claimed invention, and certainly of the concept of what is currently claimed. Applicants had possession of the polypeptide sequence in SEQ ID NO: 2; Applicants had also contemplated and provided explicit written description of polypeptides with at least 95% sequence identity to that sequence (for example, at page 9, paragraph 0032). Further, the specification describes how to determine which sequences have at least 95% sequence identity to SEQ ID NO: 2 (for example, at page 9, paragraph 0034). Methods are also provided for determining which residues are highly conserved (for example, at page 11, paragraph 0037); for making polypeptide variants

(for example, at page 12, paragraph 0038; for the generation of transgenic plants (at page 13, paragraph 0043 to page 14, paragraph 0045); and for determining if a plant (particularly a transgenic plant) produces a high oil producing phenotype (for example, at page 7, paragraph 0025 and Example 1 on pages 17-18). Therefore, based on the teachings of the specification and the knowledge of one of skill in the art, a person of ordinary skill could envision sequences having at least 95% sequence identity to the sequence set forth in SEQ ID NO: 2. The pending claims are thus sufficiently described by the specification, and Applicants request that their rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

The Office is reminded that the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶ 1, “Written Description” Requirement 66 Fed. Reg. 1099, 1106 (2001). Satisfactory disclosure of a “representative number” depends on whether one of skill in the art would recognize that Applicants were in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. *Id.* Applicants respectfully submit that one of skill in the art reading the specification would recognize that Applicants had possession of the claimed invention in its full scope at the time the application was filed. Applicants respectfully request withdrawal of the rejections of claims 1-9 and 14, for lack of adequate written description.

Rejections under 35 U.S.C. §102(b)

Claims 1-9 and 14 are rejected under 35 U.S.C. §102(b), as allegedly being anticipated by *Jako et al* and by *Zou et al*. The Office notes that these rejections are “made because the recitation ‘ortholog’ in claims 1 and 6 read on any polypeptide that has the property of increasing seed oil content” (Office action, page 17). Applicants respectfully traverse these rejections. In spite of this, and solely to advance prosecution in this case, claims 1 and 6 are amended, as discussed above, to remove reference to the term “ortholog”. It is believed that amended independent claims 1 and 6 and dependent claims 2-5, 7-9, and 14 are thus free from *Jako et al*. and *Zou et al*. Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §102(b).

Conclusion

Based on the foregoing amendments and arguments, the claims are in condition for allowance and notification to this effect is requested. If for any reason the Examiner believes that a telephone conference would expedite allowance of the claims, please telephone the undersigned at the telephone number listed below.

Respectfully submitted,

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U.S. PATENT DOCUMENTS

Copies of U.S. Patent documents do not need to be provided, unless requested by the Patent and Trademark Office. For patents, provide the patent number and the issue date. For published U.S. applications, provide the publication number and the publication date. For unpublished pending patent applications, provide the application number and the filing date.

Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
NK/		5,639,790	June 17, 1997	VOELKER and DAVIES
NK/		5,704,160	January 6, 1998	BERGQUIST <i>et al.</i>
NK/		6,229,033	May 8, 2001	KNOWLTON, Susan
NK/		6,248,939	June 19, 2001	LETO and ULRICH

FOREIGN PATENT DOCUMENTS

Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Patentee
		PCT/WIPO	WO01/083697	August 11, 2001	EXELIXIS PLANT SCIENCES, INC.

OTHER DOCUMENTS

Examiner's Initials*	Cite No. (optional)	OTHER DOCUMENTS
NK/		ANOOP <i>et al.</i> , "Modulation of citrate metabolism alters aluminum tolerance in yeast and transgenic canola overexpressing a mitochondrial citrate synthase," <i>Plant Physiol.</i> , 132:2205-2217, 2003.
NK/		BEISSON <i>et al.</i> , "Arabidopsis genes involved in acyl lipid metabolism. A 2003 census of the candidates, a study of the distribution of expressed sequence tags in organs, and a web-based database," <i>Plant Physiol.</i> , 132:681-697, 2003.
NK/		BERT <i>et al.</i> , "Comparative genetic analysis of quantitative traits in sunflower (<i>Helianthus annuus</i> L.). 2. Characterisation of QTL involved in developmental and agronomic traits," <i>Theor. Appl. Genet.</i> , 107:181-189, 2003.
NK/		CHOISNE <i>et al.</i> , Database GenEMBL, Accession No. AL049746, June 1999.
NK/		COLBERT <i>et al.</i> , "High-throughput screening for induced point mutations," <i>Plant Physiol.</i> , 126(2):480-484, 2001.
NK/		DEHESH <i>et al.</i> , "Overexpression of 3-ketoacyl-acyl-carrier protein synthase IIIs in plants reduces the rate of lipid synthesis," <i>Plant Physiol.</i> , 125:1103-1114, 2001.

EXAMINER SIGNATURE:	/Vinod Kumar/	DATE CONSIDERED:	05/27/2008
<p>* Examiner: Initial if reference considered, whether or not in conformance with MPEP 609. Draw line through cite if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>			